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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/771,895	02/04/2004	Rory F. Finn	32152	4167

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EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/771,895	FINN, RORY F.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142 applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I-XX. Claims 1-8, drawn to a method of treating 1 of 20 distinct diseases selected from the group consisting of Erectile dysfunction (I), HIV lipodystrophy (II), Fibromyalgia (III), Osteoporosis (IV), Memory disorders (V), Depression (VI), Crohn's disease (VII), Skeletal dysplasias (VIII), Traumatic brain injury (IX), Subarachnoid hemorrhage (X), Noonan's syndrome (XI), Down's syndrome (XII), Idiopathic short stature (ISS)(XIII), end stage renal disease (ESRD)(XIV), Very low birth weight (VLBW)(XV), Bone marrow stem cell rescue (XVI), Metabolic syndrome (XVII), Glucocorticoid myopathy (XVIII), Short stature due to glucocorticoid treatment in children (XIX), and Failure of growth catching for short premature children (XX); comprising administering a compound of *formula I*; classified in class 424, subclass 1.69+.

XXI-XXXX. Claims 1-8, drawn to a method of treating 1 of 20 distinct diseases selected from the group consisting of Erectile dysfunction (XXI), HIV lipodystrophy (XXII), Fibromyalgia (XXIII), Osteoporosis (XXIV), Memory disorders (XXV), Depression (XVI), Crohn's disease (XVII), Skeletal dysplasias (XVIII), Traumatic brain injury (XXIX), Subarachnoid hemorrhage (XXX), Noonan's syndrome (XXXI), Down's syndrome (XXXII), Idiopathic short stature

(ISS)(XXXIII), end stage renal disease (ESRD)(XXXIV), Very low birth weight (VLBW)(XXXV), Bone marrow stem cell rescue (XXXVI), Metabolic syndrome (XXXVII), Glucocorticoid myopathy (XXXIII), Short stature due to glucocorticoid treatment in children (XXXIX), and Failure of growth catching for short premature children (XXXX); comprising administering a compound of *formula II*; classified in class 424, subclass 1.69+.

XXXXI. Claims 9-10, drawn to a compound of *formula I*; classified in class 530, subclass 300+.

XXXXII. Claims 9-10, drawn to a compound of *formula II*; classified in class 530, subclass 300+.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XXXX and XXXXI and XXXXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process for using the product as claimed can be practiced with another materially different product, namely method of treating 1 of 20 distinct diseases selected from the group consisting of Erectile dysfunction (XXI), HIV lipodystrophy (XXII), Fibromyalgia (XXIII), Osteoporosis (XXIV), Memory disorders (XXV), Depression (XVI), Crohn's disease (XVII), Skeletal dysplasias (XVIII), Traumatic brain injury (XXIX), Subarachnoid hemorrhage (XXX), Noonan's syndrome (XXXI), Down's syndrome (XXXII), Idiopathic short stature (ISS)(XXXIII), end stage renal disease (ESRD)(XXXIV), Very

low birth weight (VLBW)(XXXV), Bone marrow stem cell rescue (XXXVI), Metabolic syndrome (XXXVII), Glucocorticoid myopathy (XXXIII), Short stature due to glucocorticoid treatment in children (XXXIX), and Failure of growth catching for short premature children (XXXX); comprising administering a compound of *formula I or formula II.*

Inventions XXXXI and XXXXII are independent and distinct, each from the other. Namely, the Inventions are drawn to distinct peptide compound formulas. The search for each of the above inventions is not co-extensive particularly with regard to a compound search of each within the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group, absent evidence to the contrary. A thorough compound of either would be independent and distinct, and thus a search of both would constitute an undue search burden.

Inventions I-XXXX are directed to different methods of use, which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group.

Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and the search required for each group is not necessarily required for the other groups, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species:

As to the compound of formula I or II, if any of Groups I-XXXXII is elected as the invention, Applicant must elect species as to: n (e.g. 1), m (e.g. 1), and R (e.g. HGH or methionyl HGH).

The species are independent or distinct because a search for any of the above species is not necessarily co-extensive particularly with regard to the literature search and a reference, which would anticipate any one of the above species, would not necessarily anticipate or even make obvious another species, absent evidence to the contrary.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 9 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not

commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecelia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 05/28/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654